patient features are required either for a one time therapeutic treatment or repeated treatments.

There are situations where the localization procedure and the therapeutic procedure must be carried out at either different times or at different locations, such as a CT scan or MR scan followed by a surgical or radiosurgical procedure.

Radiosurgical techniques, for example, employ stereotactic principles for targeting, localization and treatment. The procedure typically begins with a stereotactic reference system being fixed to the patient's skull. This reference system remains fixed relative to all intracranial points throughout the entire radiosurgical procedure. All diagnostic exams, such as angiography, CT and MR scanning include a set of fiducial markers which allow all points within the image to be localized relative to the stereotactic reference frame. All of these fiducial systems attach to the stereotactic frame in a precise and reproducible manner.

Although many prior art fixation or fiducial systems work very well for single fraction therapy, there exist clinical settings where fractionating the total dose, i.e. dividing the dose into many small fractions, would yield additional therapeutic advantages. In the radiotherapy procedure, however, once the reference frame has been removed from the patient the relationship between intracranial target points and the reference system is lost. Because the above procedure would require the reference frame to remain fixed to the patient's skull through the entire course of treatment, which may last several weeks, this approach is considered inappropriate for fractionated therapy. Alternately, each fractional treatment would require a laborious and time-consuming procedure to re-determine patient position for second and subsequent treatments.

Another typical setting occurs where the patient undergoes a medical imaging procedure to be followed by stereotactic or optic guided surgery. In this setting the patient is scanned prior to, sometimes a day or two before, the surgical procedure. The registration of

the patient's scan data set to their position on the operative setting is carried out through the use of surface fiducials. This usually entails the shaving of the patient's head.

There exist several different techniques for non-invasive repeat fixation. These methods can be broken down into three basic categories. These are bite plate systems, contour realignment systems and mask systems. All of these systems have design flaws which can lead to unacceptable, and undetectable, positional errors.

The mask techniques have been used in radiation therapy for over three decades. In these systems a custom mask, which snugly fits either the face or the entire head, is fabricated. For high precision radiotherapy the mask is then attached to a stereotactic reference frame, similar to the frame used for any stereotactic procedure. Prior to each diagnostic exam the patient is placed into the mask/frame system and normal stereotactic fiducial systems are used for image registration. Mask immobilization and repositioning systems have been used extensively in radiation therapy. By using the mask for both localization (i.e., determination of position and orientation) and positioning (i.e., the mask or mechanisms rigidly secured to it are used to move the patient), the positioning puts loads (forces and/or moments) on the mask which may distort it. Distorting the mask introduces errors which hinder the accuracy of localization.

When performing fractionated radiotherapy, accuracy in applying the radiation is very important, so that tumors or other conditions requiring radiation can receive it in relatively small volumes. Misalignment of the radiation beam may cause an insufficient amount of radiation to be applied to the tumor. Fractionated radiotherapy may be imprecise if the tumor or other target cannot be localized with a sufficient degree of accuracy. However, this need for proper localization is the same need which one has when performing single dose radiotherapy. An additional factor in fractionated radiotherapy is the need to easily and accurately repeat a position of the patient. If the position of the patient was accurate relative

to the first treatment, and relative to the imaged data set used to design the treatment, the repositioning should normally cause the patient to assume the exact same position (relative to the treatment mechanism) for the second and subsequent treatments. However, if the second or other subsequent treatment is performed with the patient only slightly removed from the first treatment position, inaccuracies will be introduced.

More generally, the need for repeat fixation of a patient or portion of a patient exists outside of the field of radiotherapy. In a typical general case, one may wish to perform a first medical procedure on a patient with a precise localization of portions of the patient, and, at some later time, perform a second medical procedure on the patient with a precise localization of the same portions of the patient. One can repeat laborious and time-consuming localization steps for the second medical procedure, but this increases medical costs and complexity. In some situations, a single medical treatment without a need for repeat fixation is the desired course of treatment. However, a high degree of accuracy in positioning of the patient may still be required.

It is now common practice for medical clinicians to obtain high contrast and high spatial resolution computerized tomography (CT) and magnetic resonance (MR) data sets. These data sets can be obtained with high spatial resolution between contiguous image slices. These data sets allow for the reconstruction of precise 3-dimensional (3D) models that accurately describe both the patient's external and internal anatomy. The patient specific models can be manipulated to provide reconstructed views along orthogonal or oblique planes through the patient's anatomy. These computed views allow for clinicians to carry out virtual treatments (or virtual planning) to better optimize therapy for a patient. Virtual planning is used in several different types of therapy. Radiosurgery, stereotactic radiation therapy, and routine radiotherapy are all therapies that rely upon virtual planning to position radiation beams. Image guided surgery relies upon virtual planning to allow the surgeon to

design and evaluate various surgical approaches and to target specific tissues. The virtual planning process places a unique requirement on the basic 3D image data set; that being the ability to track the patient, at the time of therapy, relative to the therapeutic tool. For radiosurgery, stereotactic radiation therapy and radiation therapy, the therapeutic tool is the radiation-generating device, most commonly, a medical linear accelerator. In the case of image guided surgery, the therapeutic tool can be one of a number of devices that the surgeon may use; e.g., scalpels, biopsy needles, and operating microscopes.

In order to provide the required patient-tool tracking both the tool's position and the patient's position must be known. The most common method of tracking the patient is to place identifiable reference markers, called fiducial markers, fixed relative to the portion of the patient where treatment is desired. These markers are incorporated into the 3D image data set. They are also available for identification, again on the surface of the patient (fixed relative to the portion of the patient), at the time of the therapeutic procedure. The markers on the patient are registered against their images in the 3D data set. This registration allows the computation of a rigid relationship between the virtual 3D patient and the real patient. Once this registration has been carried out, any movement of the patient can be tracked.

Although the bite plate locator technique has worked quite well for patients with intra-cranial targets, it is not as well suited for other patients. For example, patients that require therapies that significantly irritate the oral cavity can have trouble keeping the bite plate in position. Radiation therapy for head and neck cancer is one of a number of such therapies that often produce severe oral cavity inflammation.

The present invention provides a new and improved method and system for localization (i.e., proper relative positioning of a patient and a medical apparatus or system) in performing medical procedures. Thus, the present invention provides a medical method including the steps, not necessarily in order, of: positioning a patient for a first medical

procedure; molding a locator to external features of a patient, the locator being placed in registry with a portion of the patient using at least 3 fiducial markers that are fixed relative to the locator a first time to get precise positioning information relative to at least part of the patient, ***the locator remaining mechanically free*** during this step; performing a first medical procedure on the patient, ***the locator remaining mechanically free during this step***; after the first medical procedure, removing the locator from the patient; at a later time after the removing of the locator, re-attaching the locator to the patient, the locator again being in registry with the portion of the patient and having an identical orientation relative to the portion of the patient as when the locator was previously attached; after the re-attaching step, using the fiducial markers a second time to get precise positioning information relative to the at least part of the patient, ***the locator again remaining mechanically free during this step***;

It is the feature of the invention that the locator remains mechanically free during the method that constitutes the crux of the invention. It is emphasized that, by "mechanically free", is meant that the locator is not affixed to anything except the patient. It is not affixed, tethered or, in any way, fixedly tied to the apparatus employed in the procedure.

The Kormos et al '890 patent, on the other hand, relates to a detained method of performing stereotactic breast surgery by immobilizing a patient's breast, fixing the breast relative to a patient support, fixing magnetic resonant markers to the immobilization restraint, imaging the breast, specifically by magnetic resonance imaging, removing the patient from the imaging unit and performing a surgical tack along which a surgical procedure can be performed. The Kormos system is designed to immobilize an otherwise non-rigid structure, the breast, and while held into a specific position carry out a surgical procedure.

The Kormos approach differs from the claimed method in that it essentially takes otherwise non-rigid tissue and by mechanical restraint fixes it to an external reference system. Thus, note the disclosure at Col. 3, ll12-16:

> *"---The material (**12**, i.e., the 'reference mask' or "exoskeleton" as it is referred to by Kormos) is then stretched over and molded to the soft tissue region (of the patient) and affixed by clamps or other suffixing means **14** to sides of the patient support---"* (emphasis added).

There can be no interpretation of this disclosure other than that the locator is rigidly fixed to the system or apparatus employed to carry out the method.

The claimed invention, on the other hand, does not require that the patient be immobilized relative to a fixed patient support; indeed, it is specified that the reference mask system is a "mechanically free" locator. Furthermore, the invention relates specifically to a system that is not only mechanically free but also has the ability to repeatedly be fixed to the patient's rigid anatomy so that it can be used for repeat procedures. This is specifically not the focus nor the intent of the Kormos patent. In the latter the 'exoskeleton' is designed for a one-use application and then is removed and, presumably, discarded. See Col. 5, ll10-12.

The inventive approach, conversely, takes a rigid portion of the patient's anatomy and by molding a mask to the anatomy extends this rigid anatomical feature so that external fiducials can be applied. It is capable of, indeed, is designed for multiple uses and applications.

The Examiner calls specific attention to the disclosure of Kormos at col. 3, lines 23-26 that states:

> *"---exoskeleton---is sufficiently stiff to hold the soft tissue substantially **fixed relative to itself**---"*(emphasis Examiner's).

It is not seen how this helps the Examiner's position since it only underscores the fact that the exoskeleton is fixed to the soft tissue. The Examiner has overlooked that portion of the disclosure cited above by applicant that states that the exoskeleton is also *affixed by clamps or other affixing means **14** to sides of the patient support.* Since the reference directly and unequivocally contraindicates the mechanically free locator of the present invention, the

reference cannot be said to anticipate the claimed invention within the meaning of 35 USC 102(b).

Accordingly, withdrawal of this ground of rejection is respectfully requested.

The rejection of claims 1-8, 10-14, 17-18, and 20-22 over 35 USC 103 as obviously unpatentable over Kormos '890 in view of McLaurin is respectfully traversed. Notwithstanding the Examiner's comments regarding the disclosure of the secondary reference, the fact remains that the reference does not cure the deficiencies pointed out above in connection with the primary reference to Kormos. More particularly, McLaurin does not disclose or suggest the use of a 'mask' or 'exoskeleton' that is mechanically free, i.e., that is not affixed to the patient support or locator.

The McLaurin patent is, like that of Kormos, an immobilization system for fixing a patient. Applicants specifically discuss ion the specification that immobilization of the patient is not the preferred method of referencing. This technique has been applied over many years and has shown limited clinical success. The entire focus of the present invention is the use of, e.g., a facemask that is rigid and fixes the patient relative to a second reference system. The proposed improvement of this system is that the second reference system, the bar references, which is similar to those used for stereotactic head frame application, is added to the mask system. The reference bars are relative to the frame system and not the patient. The difficulty in this approach is that it is known that the patient does not repeatedly position in the reference frame mask if the mask is used for immobilization and localization. The reference frame, the bar system, is therefore not rigidly fixed to the patient's anatomy. In the claimed approach we specifically maintain the reference system "mechanically free" to allow the reference system to more precisely reseat to the patient's external anatomy. This separation of immobilization and localization is the key difference between the claimed invention and the prior art approaches.

A legal conclusion of patent invalidity for obviousness must be supported by findings on the four factual inquiries set forth in *Graham v. John Deere Co.*, [383 U.S. 1, 148 USPQ 459 (1966)].

Precedent clearly establishes that the fact-finder must make Graham findings before invalidating a patent for obviousness. See *Jones v. Hardy*, 727 F.2d 1524, 1529, 220 USPQ 1021,1025 (Fed. Cir. 1984)); *Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc.*, 807 F.2d 955, 961, 1 USPQ2d 1196, 1200 (Fed. Cir. 1986); In *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 228 USPQ 90 (Fed. Cir. 1985), it was stated:

> "---In patent cases, the need for express Graham findings takes on an especially significant role because of an occasional tendency --- to depart from the Graham test, and from the statutory standard of unobviousness that it helps determine, to the tempting but forbidden zone of hindsight. Thus, we must be convinced --- that--- Graham (was actually applied)--" The necessity of Graham findings is especially important where the invention is less technologically complex, [In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999)]. In such a case, the danger increases that the very ease with which the invention can be understood may prompt one to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.---"

Thus, the legal conclusion of invalidity for obviousness depends on four factual inquiries identified by Graham v. John Deere Co. as concerning (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) secondary considerations of nonobviousness.

In the present case the Examiner has erred by failing to conduct a Graham analysis. Indeed the Examiner has failed to even mention Graham, much less analyze the disclosures of the prior art.

In order to justify a combination of references, it is necessary not only that it be physically possible to combine them, but also that the art should contain something to suggest the desirability of doing so. Ex parte Walker, 135 USPQ 195; Ex parte Fleischmann, 157 USPQ 155. The prior art cannot be combined as if appellant's invention was included therein as a part of the knowledge possessed by one of ordinary skill in the art. In combining

references, the prior art references themselves must suggest their being combined so as to render the claimed invention obvious to one skilled in the art; and resort must not be had to applicant's own disclosure and the utilization of hindsight for the guiding hand that dictates the combination of references.

It is further well settled that the prior art itself must suggest the problem sought to be solved by the claimed invention before it can be said to suggest or disclose its solution. In re Shaffer, 108 USPQ 326; In re Aufhauser, 158 USPQ 351; US v. Adams 148 USPQ 479; In re Nomiya, 184 USPQ 607.

Any analysis of obviousness must necessarily begin in the text of section 103, with the phrase "at the time the invention was made." For it is this phrase that guards against entry into the "tempting but forbidden zone of hindsight," [see *Loctite Corp. v, Ultraseal Ltd.*, 781 F.2d 861,873; 228 USPQ 90,98 (Fed. Cir. 1985), overruled on other grounds by *Nobel-pharma AB v. Implant Innovations, Inc.*, 141 F. 3d1059, 46USPQ2d 1097 (Fed. Cir, 1998)], when analyzing the patentability of claims pursuant to that section.

Measuring a claimed invention against the standard established by section 103 requires the often difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. See, e.g., *W.L Gore & Assoc., Inc. y. Garlock, Inc.*, 721 F.2d 1540, 1553, 220 UPSQ 303, 313 (Fed. Cir 1983). Close adherence to this methodology is especially important in the case of less technologically complex inventions, where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." *Id.*

The present state of the patent law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of

the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F. 3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998,) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding") *In re Rouffet*, 149 F.3d 1350, 1359; 47 USPQ2d 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically---the reasons one of ordinary skill in the art would have been 'motivated to select the references and combine them"); *In re Fritch* 972 F.2d 1260, 1265; 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); *In re Fine*, 837 F.2d 1071, 1075; 5 USPQ2d 1596, 16O0 (Fed Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); *Ashland Oil, Inc. v. Delta Resins*, 776 F.2d 281, 297, 227 USPQ 657, 667 (Fed Cir. 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also *Graham* 383 U.S. at 18, 148 USPQ at 467 ("strict observance" of factual predicates to obviousness conclusion required).

Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability-the essence of hindsight. See, e.g., *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132 1138, 227 USPQ 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case, the Board (Examiner) has obviously fallen into the hindsight trap.

Courts have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, see *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 I F.3d 1568, 1573; 37 USPQ2d 1626, 1630 (Fed. Cir.

1996), *Para-Ordinance Mfg. v. SGS Imports Intern., Inc.*, 73 F.3d 1085, 1088; 37 USPQ2d 1237, 1240 (Fed. Cir. 1995), although "the suggestion more often comes from the teachings of the pertinent references," *Rouffet*, 149 F.3d at 1355, 47 USPQ2d at 1456. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. See, e.g., *C. R. Bard*, 157 F.3d at 1352; 48 USPQ2d at 1232. Broad conclusory statements regarding the teachings of multiple references, standing alone, are not "evidence." *E.g., McElmurry V. Arkansas Power &. Light Co.*, 995 F.2d 1576, 1578; 27 USPQ2d 1129, 1131 (Fed. Cir. 1993) ("Mere denials and conclusory statements, however, are not sufficient to establish a genuine issue of material fact."); *In re Sichert*, '566 F.2d 1154, 1164, 196 USPQ ~209, 217 (CCPA 1977).

It is clear that the authorities are unanimous in holding that it is impermissible to use the claimed invention as an instruction manual or "template" to piece together isolated disclosures and teachings of the prior art so that the claimed invention may be rendered obvious. A rejection based on § 103 must rest on a factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See *In re Warner*, 379 F.2d 1011, 1017, 154 USPQ 173, 178 (CCPA 1967), cert. denied, 389 U.S. 1057 (1968). Since there is no factual basis in the prior art relied on which supports the proposed combination thereof, and it is apparent that the examiner's conclusion of obviousness is based on hindsight reconstruction of the claimed invention from isolated disparate teachings in prior art which is not concerned with the problem sought to be solved by the claimed invention, this ground of rejection is not sustainable.

It is clear that the Examiner, in making the analysis that led to the present ground of

rejection, fell into the trap of hindsight reconstruction of the invention from the reference disclosures in light of applicant's specification.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

The prior art cited by the Examiner but not relied upon has been carefully reviewed. In contrast to the system of Chader, the proposed system uses a molded mask to key to the patient's anatomy specifically for the purpose of repeat fixation. It is specified that the mask be fixed to the anatomy while being mechanically free of any other immobilization or fixation system.

Applicants have earnestly endeavored to place this application in condition for allowance and an early action to that end is respectfully requested.

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Respectfully submitted,

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